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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/352,570	07/13/1999	MICHAEL E. MENDELSON	00398/506001	2454

21559 7590 03/23/2004

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/352,570

Applicant(s)

MENDELSON, MICHAEL E.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 13 August 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 13 August 2003, have been fully considered but they are not found persuasive.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2004 has been entered.

Specification

4. The amendment filed 30 September 2002 (Paper No. 15) and the amendment to the paper sequence listing are objected to under 35 U.S.C. 132 because it introduces

new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. Applicant is required to cancel the new matter in the reply to this Office Action.

The amendment to specification on pages 16 and 20 to change the amino acid to nucleic acid because the protein does not have the specific amino acid length would not be recognized by one of skilled in the art. The typographical errors could have occurred anywhere including the position of the amino acid sequence and not necessarily the nucleic acid sequence. Furthermore, the specification does not refer to the specific nucleic acid position in the specification nor its interaction with MAD2.

The paper Sequence Listing amendment to add SEQ ID NO:5-7 is new matter which was not disclosed in the original specification.

Applicants request that the amendment be withdrawn. Amendments cannot be withdrawn. Amendments may be filed to correct the defect.

Claim Rejections - 35 USC § 112

5. Claims 1-3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite terms "estrogen receptor beta", "mitosis arrest deficient 2", "ER beta", "MAD2", or GST-ER β " which is ambiguous because it is not clear what is the metes and bounds of the terms which has no structural limitations. Applicants argue

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that identifying the acronym with the name overcomes the rejection. However, the rejection is based upon the lack of structural limitations which makes it unclear what is the metes and bounds of the terms. Claims 2, 3, and 6 are dependent on claim claims 1.

Applicants argue that based on the knowledge in the art, the terms ER/ and MAD2, in the absence of any additional structural detail, would be sufficient to establish the metes and bounds of these terms in the claims. However, the names change and different scientist call the same proteins by different names.

Claim Rejections - 35 USC ' 112, first paragraph

6. Claims 1-3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 recite terms "estrogen receptor beta", "mitosis arrest deficient 2", "ER beta", "MAD2", or GST-ER β " which encompasses a variant protein because no structural limitations is provided. Claims 2, 3 and 6 are dependent on claim claims 1. However, the specification discloses working example of species of MAD2 and ER beta which is the essential feature of the invention. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the disclosure does not have written description for the genus of

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variants. One skilled in the art cannot envision the sequence of all the variants of proteins encompassed by the claim limitation.

Applicants argue that the function of ER beta and MAD2 polypeptides identified from several different organisms was well documented prior to the filing date of the present specification, and the terms ER beta and MAD2 in the present claims would adequately convey to the skilled artisan. However, the specific scientific references are referring to the species that are being experimented with. The specification appears to describe a genus of molecules as encompassing these terms.

Applicant argue that the functional properties of these polypeptides are clearly described in the specification. However, the terms are not limited by structure and the genus encompassed by the term is unlimited. *Eli Lilly* clearly indicated unreasonable genus limited by terms without structure is not patentable. *Eli Lilly* did not allow generic terms such as mammalian or vertebrate.

Claim Rejections - 35 USC § 102

7. Claims 1, 3 6, 9, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by lafrati et al.(Nature Medicine, 1997).

lafrati et al. teach the method of determining vascular cell proliferation when treated with estradiol which expresses estrogen receptor beta (page 546 and figure 3). The vascular cells inherently expresses the MAD2.

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Applicants argue that the steps of the method of claim 1 is not taught in by lafrati et al. However, lafrati et al. clearly discusses the cell proliferation which is a indicator of cell division.

Applicants argue that the examiner must provide some evidence in the prior art that describes the missing elements. It should be noted that terms "estrogen receptor beta" or "MAD2" are not structurally limited and encompass many different compounds not just the species in the working example. lafrati et al. disclose effect on cell division. Furthermore, Elledge (Science, 1998, IDS) teaches that MAD2 are ubiquitous in all cell division.


8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Michael Pak
Primary Patent Examiner

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30 January 2003